

CLAIMS

Sub 1. A method for non-invasively determining a condition of the circulatory system of a subject, the subject inhaling and exhaling breathing gases during breathing, said method comprising the steps of:

5 (a) measuring the amount of CO₂ in the breathing gases exhaled by the subject and the CO₂ concentration of the breathing gases exhaled by the subject for a first (1) breathing condition of the subject;

(b) determining at least one value of the amount of CO₂ released from the circulatory system of the subject (VCO₂¹) using the amount of CO₂ in the breathing gases exhaled when the subject is in the first condition;

10 (c) determining at least one value for a quantity indicative of the end capillary blood CO₂ content of the subject using the CO₂ concentration of the breathing gases exhaled when the subject in the first condition;

(d) altering the CO₂ concentration in the lungs of the subject;

15 (e) measuring the amount of CO₂ in the breathing gases exhaled by the subject and the CO₂ concentration of the breathing gases exhaled by the subject for at least one breath of the subject under second (2) breathing conditions of altered CO₂ in the lungs of the subject;

20 (f) determining at least one value for the amount of CO₂ released from the circulatory system of the subject (VCO₂²), the determination of the value being carried out in a time period less than that required for blood leaving the lungs of the subject to pass through the circulatory system of the subject and return to the lungs, the determination of the value using the amount of CO₂ in the exhaled breathing gases for the second breathing condition;

25 (g) determining at least one value for a quantity indicative of the end capillary blood CO₂ content of the subject, the determination of the value being carried out in a time period less than that required for blood leaving the lungs of the subject to pass through the circulatory system of the subject and return to the lungs, the determination of the value using the CO₂ concentration of the breathing gases

exhaled for the second breathing condition; and

30 (h) performing a regression analysis using the determined VCO_2^1 , VO_2^2 , and end capillary blood CO_2 quantity values to establish a regression line; and

(i) extrapolating the regression line to obtain a value for the end capillary blood CO_2 quantity when the amount of CO_2 released from the
35 circulatory system of the subject (VCO_2) is zero.

2. The method according to claim 1 wherein steps (a) and (e) are further defined as measuring end tidal CO_2 concentrations of the breathing gases exhaled by the subject.

3. The method according to claim 2 further defined in that the quantity, for which values are determined in steps (c) and (g), comprises the end tidal CO_2 concentration of the exhaled breathing gases and that the value obtained in step (i) is the end tidal CO_2 concentration when the amount of CO_2 released
5 from the circulatory system of the subject (VCO_2) is zero.

4. The method according to claim 1 further defined in that the quantity, for which the values are determined in steps (c) and (g), comprises the CO_2 partial pressure in the blood of the subject and that the value obtained in step (i) is the CO_2 partial pressure of the end capillary blood of the subject when the
5 amount of CO_2 released from the circulatory system of the subject (VCO_2) is zero.

5. The method according to claim 1 or 2 further defined in that the quantity, for which the values are determined in steps (c) and (g), comprises the CO_2 content of the end capillary blood ($CcCO_2$) of the subject and that the value obtained in step (i) is the CO_2 content of the end capillary blood of the subject
5 when the amount of CO_2 released from the circulatory system of the subject

(VCO₂) is zero, which value comprises the CO₂ content of venous blood (CvCO₂).

SUB 11
6. The method according to claim 1, 2, 3, 4 or 5 further including the step of using the value obtained in step (i) to determine the functional cardiac output (FCO) of the subject using a non-differential form of the Fick equation.

7. The method according to claim 1, 2, 3, 4 or 5 further defined as including the steps of:

5 determining further values for the amount of CO₂ released from the circulatory system of the subject (VCO₂) and for the quantity indicative of the end capillary blood CO₂ content for breathing of the subject in the first breathing condition; and

10 using the value provided by the extrapolation of the regression line in step (i) and a further determined released CO₂ amount (VCO₂) and value for the quantity indicative of end capillary blood CO₂ content to determine the functional cardiac output of the subject using a non-differential form of the Fick equation.

8. The method according to claim 7 further defined as being carried out on a breath-by-breath basis.

SUB 12
9. The method according to claim 1, 2, 3, 4 or 5 further including the steps of:

5 determining a further value for the quantity indicative of the end capillary blood CO₂ content for breathing of the subject in the first breathing condition;

forming a relationship between the value for the quantity indicative of the end capillary blood CO₂ content for breathing in the first breathing condition used in the regression analysis and the value obtained by extrapolating the regression line in step (i); and

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applying the relationship to the further determined value for a quantity indicative of the end capillary blood CO₂ content to provide a new value for the value which was obtained by the extrapolation of the regression line in step (i).

10. The method according to claim 9 further defined as forming a relationship comprising as a ratio.

11. The method according to claim 9 further defined as forming a relationship comprising a difference.

12. The method according to claim 9, 10 or 11 further including the steps of:

determining further values for the amount of CO₂ released from the circulatory system of the subject (VCO₂^N) for breathing of the subject in the first breathing condition; and

using the further determined released CO₂ amount (VCO₂¹), the further determined value for a quantity indicative of the end capillary blood CO₂ content, and the new value for the value which was obtained by extrapolation of the regression line in a non-differential form of the Fick equation to determine the functional cardiac output (FCO) of the subject.

13. The method according to claim 9, 10, 11 or 12 further defined as being carried out on a breath-by-breath basis.

14. The method according to claim 1 wherein the step of altering the CO₂ concentration in the lungs of the subject is further defined as increasing the CO₂ concentration in the lungs of the subject to reduce CO₂ gas exchange in the lungs of the subject.

15. The method according to claim 14 wherein the step of increasing the CO₂ concentration in the lungs of the subject is further defined as increasing the CO₂ content of the breathing gases inhaled by the subject.

16. The method according to claim 15 further defined as administering a bolus of CO₂ into the breathing gas inhaled by the subject.

17. The method according to claim 15 further defined as causing the subject to inhale breathing gas previously exhaled by the subject.

18. The method according to claim 15 wherein step (d) is further defined as increasing the CO₂ by an amount which improves the accuracy of the determination while avoiding undue build up of CO₂ in the blood of the subject.

19. The method according to claim 1 wherein the step of altering the CO₂ concentration in the lungs of the subject is further defined as decreasing the CO₂ concentration in the lungs of the subject to increase CO₂ gas exchange in the lungs of the subject.

20. The method according to claim 19 wherein the step of decreasing the CO₂ concentration in the lungs of the subject is further defined as increasing the ventilation of the subject.

21. The method according to claim 5 further defined as including the steps of :

determining the amount of oxygen in the venous blood of the subject;

and

altering the obtained value for the venous blood CO₂ content

(CvCO₂) in accordance with the amount of oxygen in the blood to provide a CO₂ partial pressure value (PvCO₂) for venous blood.

22. The method according to claim 21 wherein the step of the determining the amount of oxygen in the venous blood is further defined as determining the degree of oxygen saturation of the venous blood.

23. The method according to claim 21 further defined as including the steps of:

determining a further value for the quantity indicative of the end capillary blood CO₂ content for breathing of the subject in the first breathing condition;

forming a relationship between the value for the quantity indicative of the end capillary blood CO₂ content for breathing in the first breathing condition used in the regression analysis and the CvCO₂ value obtained by extrapolating the regression line in step (i);

applying the relationship to the further determined value for a quantity indicative of the end capillary blood CO₂ content to provide a new CvCO₂ value; and

altering the new CvCO₂ value in accordance with the amount of oxygen in the blood to provide a new CO₂ partial pressure value (PvCO₂) for venous blood.

24. The method according to claim 23 further defined as forming a relationship comprising a ratio.

25. The method according to claim 23 further defined as forming a relationship comprising a difference.

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26. The method according to claim 21, 22, 23, 24 or 25 further defined as carrying out the method on a breath-by-breath basis.

27. The method according to claim 1 further defined as performing linear regression analysis using the VCO_2^1 , VO_2^2 , and 1 and 2 values for the quantity indicative of the end capillary blood CO_2 content of the subject.

28. The method according to claim 1 where the breathing gases supplied to the subject comprise air.

29. The method according to claim 1 further including the step of allowing the subject to take a sufficient number of breaths to stabilize the CO_2 content and CO_2 concentration of the exhaled breathing gases before taking the breathing measurements for the first breathing condition of the subject.

30. The method according to claim 1 further defined as determining a plurality of values for at least one of the amount of CO_2 removed from the lungs of the patient (VCO_2) and the quantity indicative of the end capillary blood CO_2 content for use in performing the regression analysis.

31. The method according to claim 1 wherein steps (b) and (f) are further defined as determining at least one value of the amount of CO_2 released from the circulatory system of the subject (VCO_2) using the CO_2 content of the inhaled and exhaled breathing gases.

32. A method for determining a change in a measured condition of the circulatory system of a subject, said method comprising the steps of:

(a) non-invasively obtaining an initial value for at least one

selected variable capable of indicating changes in a measured circulatory system
5 condition of the subject;

(b) carrying out a discrete measurement of a circulatory system
condition of a subject;

(c) obtaining a further value for the at least one selected variable
subsequent to carrying out the discrete measurement

10 (d) comparing the subsequent value of the variable with the initial
value of said variable to determine whether the obtained variable has changed in
value.

33. The method according to claim 32 wherein the selected
variable comprises at least one of exhaled CO₂ amount, end tidal CO₂ amount,
heart rate, and the amount of CO₂ released from the blood of the subject (VCO₂).

34. The method according to claim 32 further defined as
compensating the values of the selected indicator variable for changes in the
condition of the subject not arising from circulatory system conditions.

35. The method according to claim 34 further defined as
compensating a selected indicator variable for changes in ventilation of the subject.

36. The method according to claim 32 wherein the discrete
measurement of circulatory system condition in step (b) is carried out using Fick
Equation 1 and the quantities expressed therein and the circulatory system condition
is the functional cardiac output (FCO).

37. The method according to claim 32 wherein the discrete measurement of circulatory system condition in step (b) is carried out using Fick Equation 2 and the quantities expressed therein.

38. The method according to claim 37 wherein the at least one selected variable further comprises at least one of the amount of CO_2 released from the blood of the subject (VCO_2) and the end tidal CO_2 amount for normal conditions of the subject.

39. The method according to claim 37 wherein the measured circulatory system condition is functional cardiac output (FCO).

40. The method according to claim 32 wherein the discrete measurement of circulatory system condition is carried out using the quantities expressed in Fick Equation 2 and the circulatory system condition is venous blood partial CO_2 pressure (PvCO_2).

41. The method according to claim 39 wherein the at least one selected variable further comprises at least one of the amount of CO_2 released from the blood (VCO_2) and end tidal CO_2 for normal conditions of the subject.

42. The method according to claim 32 wherein the discrete measurement of the circulatory system condition in step (b) is carried out using a blood dilution technique.

43. The method according to claim 42 wherein the blood dilution

technique uses a marker dye.

44. The method according to claim 42 wherein the blood dilution technique uses thermodilution.

45. The method according to claim 42 wherein the circulatory system condition measured is cardiac output (CO).

46. The method according to claim 32 wherein step (c) is further defined as sequentially obtaining further values of the at least one selected variable for comparison with the initial value.

47. The method according to claim 46 further defined as obtaining further values on a breath-by-breath basis.

48. The method according to claim 46 further defined as obtaining further values on a heart beat by heart beat basis.

49. The method according to claim 32 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

50. The method according to claim 37 further defined as allowing disturbances caused by the carrying out of the discrete measurement to subside before obtaining a further value for said at least one selected variable.

51. The method according to claim 32 wherein step (d) is further defined as determining whether the variable has changed by a predetermined amount.

52. The method according to claim 32 further defined as initiating an action responsive to a change in the variable.

53. The method according to claim 52 further defined as initiating a further carrying out of a discrete measurement of a circulatory system condition of the subject.

54. The method according to claim 52 further defined as providing an indication that a change in the value of the variable has occurred.

55. The method according to claim 52 further defined as providing an indication of the amount by which the value of the variable has changed.

56. The method according to claim 52 further defined as providing an indication of the direction in which a change in the value of the variable has occurred.

57. The method according to claim 52 further defined as providing an alarm.

58. Apparatus for determining a change in a measured condition of the circulatory system of a subject, said apparatus comprising:

5 (a) means for non-invasively obtaining initial and subsequent values for at least one selected variable capable of indicating changes in a measured circulatory system condition of the subject;

(b) means for carrying out a discrete measurement of a circulatory system condition of a subject; and

10 (c) means for comparing a subsequent value of the variable with the initial value of said variable to determine whether the obtained variable has changed in value.

59. The apparatus according to claim 58 wherein the selected variable comprises at least one of exhaled CO₂ amount, end tidal CO₂ amount, heart rate, and the amount of CO₂ released from the blood of the subject (VCO₂).

60. The apparatus according to claim 58 further defined as including means for compensating the values of the selected indicator variable for changes in the condition of the subject not arising from circulatory system conditions.

61. The apparatus according to claim 58 wherein the measured circulatory system condition is functional cardiac output (FCO).

62. The apparatus according to claim 58 wherein the measured circulatory system condition is venous blood partial CO₂ pressure (PvCO₂).

63. The apparatus according to claim 58 wherein the measured circulatory system condition is cardiac output.

64. The apparatus according to claim 58 wherein the circulatory system condition is measured non-invasively.

65. The apparatus according to claim 58 wherein the circulatory system condition is measured invasively.

66. The apparatus according to claim 58 further defined as means for initiating an action responsive to a change in the variable.

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